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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,476	09/09/1999	THERESA C. WHITE	1039.2500-CI	1211

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EXAMINER

WAX, ROBERT A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,476

Applicant(s)

WHITE ET AL.

Examiner

Robert A. Wax

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-29,32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicants' arguments and amendments in the response filed July 6, 2004, with respect to the rejections of claims 1-33 under 35 USC 101, 35 USC 112, first paragraph, written description and claims 1-30 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, these rejections have been withdrawn. However, upon further consideration, new grounds of rejection are made under 35 USC 112, second paragraph ("fungi" inappropriate), 35 USC 102(b) (claims 22 and 23 define a product by process) and 35 USC 103 (in view of the discovery of the Xin-Liang et al. reference).

Terminal Disclaimer

2. The terminal disclaimer filed on July 6, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent No. 6,015,703 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-21 and 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1653

Claims 8-18 and 26-29 recite "filamentous fungi" which improperly matches the number. The plural term "fungi" should be replaced by the singular form, "fungus".

Recitation of "a fungi" is not correct grammar.

Claim 10 contains the improper name *Penicillum*, which needs to be deleted.

Claims 19-21 are indefinite because purification of the protein of interest is not a part of the step of "causing the fungi to produce" but it is a permitted further step of the method of producing the protein of interest. Deletion of "wherein the step of causing the fungi to produce," and amending "comprises" to "comprising" will overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by hemoglobin.

Claims 22 and 23 are directed to any protein produced by the process of claims 14 and 20, respectively. Since the claims are not limited to any particular protein, and the patentability of a product by process claim relies on the product, hemoglobin produced by the claimed processes would be identical to hemoglobin produced by any

Art Unit: 1653

other process and thus the existence of hemoglobin clearly anticipates the above claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 4-29, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suominen et al. in view of Xin-Liang et al.

The teachings of Suominen et al. have been discussed thoroughly during prosecution. They teach genetic constructs comprising the cbh1 promoter, xln1 secretion signal and xln1 coding region. As applicants have correctly pointed out, Suominen et al. do not explicitly teach use of the xln1 secretion signal to express proteins other than xln1. This is why the previous rejection under 35 USC 102(b) has been withdrawn. However, again as applicants point out, "Suominen et al. . . . suggest that the coding sequence should retain its own signal sequence, except under certain circumstances. On page 26, lines 12-17 it is indicated that if a desired protein does not possess its own signal sequence, or the signal sequence does not function well in *Trichoderma*, then the coding sequence may be operably linked to a signal sequence homologous or heterologous to *Trichoderma*. However, no specific examples of a desired signal sequence, nor any evidence of the benefit of a specific signal sequence,

Art Unit: 1653

is provided by Suominen et al. The deficiencies of Suominen et al. are remedied by Xin-Liang et al.

Xin-Liang et al. teach a xylanase signal sequence from *Saccharomyces cerevisiae*, APX-II (see column 7, lines 23-48) that may be used to express heterologous proteins, i.e., proteins that are not xylanase (see column 8, lines 29-31). Host cells useful for expression of such heterologous proteins include filamentous fungi, including *Trichoderma*, see column 8, lines 31-51, especially lines 42-49. Xin-Liang et al. state that "the APX-II signal peptide cDNA coding sequence in combination with a suitable foreign gene expressible in *S. cerevisiae* are prepared with the gene under control of a promoter expressible in the host, preferably *S. cerevisiae*" at column 8, lines 60-67. Clearly, this teaching is extendible to mean that if the host is not *S. cerevisiae* then a promoter that is expressible in that host should be used.

It would have been obvious to one of ordinary skill in the art at the time the invention was made express heterologous genes in the system of Suominen et al. under control of the xylanase signal sequence as taught by Xin-Liang et al. with the expectation of overproducing the heterologous protein. This expectation is raised by the teachings of Xin-Liang et al. at column 35, line 26-column 36, line 18 where they compare expression of proteins under the control of APX-II vs. two other signal peptides. They show that APX-II is more efficient.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax
Primary Examiner
Art Unit 1653

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